K140133

MAY 15 2014

**Section 5. 510(k) Summary**

**K Number** _____

**Submission Date:** January 16, 2014

**General Information**

| | |
|---|---|
| Classification | Class II |
| Trade Name | Infuset™ Flow Control Extension Set |
| Common Name: | I.V. Flow Controller |
| Classification Name and Reference: | Intravascular Administration Set<br>21 CFR §880.5440 |
| Submitter | Peter Kollings<br>EMED Technologies Corporation<br>1264 Hawks Flight Ct., Ste. 200<br>El Dorado Hills, Ca 95762<br>Tel: 916.932.0071 x114<br>Fax: 916.932.0074 |

**Intended Use**

Infuset™ Flow Control Extension Sets are intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.

**Predicate Device(s)**

Freedom 60 Syringe Infusion Pump System (K933652)

**Device Description**

EMED Infuset™ Flow Control Extension Sets are disposable devices allowing users to obtain a controlled and precise rate of fluid flow when used with the RMS Freedom 60 Syringe Infusion Pump System.

Each Infuset™ Flow Control Extension Sets consist of a given length of medium-density PVC tubing and rigid PVC standard luer lock connectors. Robust componentry and bonding techniques allow the Infuset™ Flow Control Extension Sets to withstand fluid pressures up to 25 psi. These sets can be physically connected to fluid sources

compatible with the Freedom60 Syringe Infusion System and patient administrations sets using the standard luer lock connectors. The Infuset™ Flow Control Extension Sets are provided sterile for single use.

The Infuset™ Flow Control Extension Sets rely upon the properties inherent to the static fluid path dimensions dictated by the Infuset™ Flow Control Extension Set length and tubing inner diameter to provide a precise, controlled flow rate. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid. Available configurations with differing lengths and tubing diameters offer users several target flow rates to choose from.

This basic construction and principle of action are essentially identical to that of the predicate flow control accessory that has had market clearance and been actively marketed for decades.

**Materials and Characteristics**

Infuset™ Flow Control Extension Sets are equivalent in performance, physical properties, using similar materials, and having the same indications for use as the predicate. Therefore no new issues of safety or effectiveness are introduced by the minimal differences in design.

Table 5-1 below provides a comparison of technological and other characteristics of the EMED Infuset™ Flow Control Extension Sets and the predicate.

**Table 5-1**

| | **Infuset™ Flow Control Extension Sets** | **RMS Precision Flow Rate Tubing Sets (K933652)** |
|---|---|---|
| Indications for Use | Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system. | Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system. |
| Material | PVC | PVC |
| Design – Lengths | 7.5 cm - 97 cm | 34.3 cm - 100 cm |
| Design – components | Male Luer Lock<br>Tubing<br>Female Luer Lock<br>Slide Clamp | Male Luer Lock<br>Tubing<br>Female Luer Lock<br>Slide Clamp |

| | Infuset™ Flow Control Extension Sets | RMS Precision Flow Rate Tubing Sets (K933652) |
|---|---|---|
| | | |
| Design – Approximate Residual Volume | 0.10 – 0.20 ml | 0.01 – 0.09 ml |
| Principle of Flow Rate Control | The internal fluid path dimensions of each Infuset configuration is fixed, thereby providing a single flow rate for each configuration. | The internal fluid path dimensions of each RMS flow rate tubing set configuration is fixed, thereby providing a single flow rate for each configuration. |
| Method of Sterilization | Ethylene Oxide (ETO) | Radiation |

**Performance**

Table 5-2 below summarizes testing results performed to establish conformance of the Infuset™ Flow Control Extension Sets to internal product specifications and requirements, as well as equivalence to the predicate device.

**Table 5-2**

| | Infuset™ Flow Control Extension Sets | RMS Precision Flow Rate Tubing Sets (K933652) |
|---|---|---|
| Flow Rate Control<br><br>(0.9% saline at 20-23°C, with Freedom60) | Range:<br>202-2244 ml/hr<br><br>Precision<br>Less than 5% RSD<br><br>Accuracy:<br>+/- 10% | Range:<br>47 - 1743 ml/hr<br><br>Precision<br>Less than 5% RSD<br><br>Accuracy:<br>-27% to + 38% |
| Pressure | Not Less than 25 psi | Not Less than 15 psi |

The outcomes of these tests further indicate that the Infuset™ Flow Control Extension Set is substantially equivalent to the predicate accessory in performance, effectiveness, and safety.

**Biocompatibility**

In accordance with ISO 10993-1:2009 and based on the intended use of the Infuset™ Flow Control Extension Sets, studies were performed including the following: cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, and hemocompatibility. Table 5-3 presents a summary of testing and results indicating compliance with biocompatibility standards.

**Table 5-3**

| Standard | Test Name | Test Result | Other Name |
|---|---|---|---|
| ISO 10993-5 | Cytotoxicity | Pass | Neutral Red Uptake |
| ISO 10993-10 | Sensitization | Pass | Kligman Maximization |
| ISO 10993-10 | Irritation | Pass | Intracutaneous Injection |
| ISO 10993-11 | Acute systemic toxicity | Pass | Systemic Injection |
| ISO 10993-11 | Pyrogenicity | Pass | Rabbit Pyrogen |
| ISO 10993-4 | Hemocompatibility | Pass | Unactivated Partial Throbmoplastin Time |
| ASTM 756 | Hemocompatibility | Pass | Hemolysis (complete) |
| USP <85> | LAL Endotoxin Test | Pass | LAL Endotoxin Quantitation Test (Kinetic-QCL Method) |

**Sterility, Shelf-life, and Packaging**

The Infuset™ Flow Control Extension Sets will be sterilized to a sterility assurance level (SAL) of $10^{-6}$ and with a shelf life of 5 years.

**Summary of Substantial Equivalence**

EMED Technologies Corporation Infuset™ Flow Control Extension Sets are substantially equivalent to the commercially available predicate device accessory in terms of function, safety, performance, intended use, technology/principles and mechanical properties. Differences between the EMED Infuset™ Flow Control Extension Sets and the predicate do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

EMED Technologies Corporation
Peter Kollings
Director Regulatory Affairs and Quality Assurance
1264 Hawks Flight Ct., Ste. 200
El Dorado Hills, CA 95762

Re: K140133

Trade/Device Name: Infuset Flow Control Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: April 11, 2014
Received: April 15, 2014

Dear Mr. Kollings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,


Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K140133

Device Name
Infuset™ Flow Control Extension Set

Indications for Use *(Describe)*
The Infuset™ Flow Control Extension Set is intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a contained to a patient's vascular system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2014.05.15 11:50:03 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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